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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/852,666	05/07/97	CHADA	CMZ-1.0-057C

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EXAMINER	
WILSON, M	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/852,666	Applicant(s) Kirin K. Chada
	Examiner Wilson, Michael C.	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *1* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-40* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-40* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

1. The declaration claims benefit under 35 U.S.C. 120 to application 08/697529, but it should be 08/679,529. A continuation-in-part application requires the proper disclosure of prior applications. A new declaration is required.

The specification fails to comply with the sequence rules as the claims do not contain Sequence ID numbers.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, and 39-40, drawn to a model for disease, specifically transgenic mammals with an inactivated HMGI, classified in class 800, subclass 2.

II. Claims 6-12, 18, and 20-22, drawn to methods for treating obesity by breeding a mammal with an inactivated HMGI gene, classified in class 435, subclass 172.3.

III. Claims 6-13, 17-19, 23-26, and 30-32, drawn to a method for treating obesity by reducing the bioactivity of HMGI by administering antisense molecules, classified in class 514, subclass 1+.

IV. Claims 6-12, 14, 15-19, 23-25, 27-28, and 30-32, drawn to a method for treating obesity by inhibition of the DNA binding activity of HMGI, classified in class 435, subclass 172.3.

V. Claims 6-12, 16-19, 23-25, and 29-32, drawn to a method for treating obesity by inhibition of the protein:protein interactions of HMGI protein, classified in class 514, subclass 12.

VI. Claims 33-35, drawn to a method for screening compounds' ability to inhibit HMGI activity *in vitro* by determining their binding affinity, classified in class 435, subclass 7.1.

VII. Claims 36-38, drawn to a method of screening compounds' ability to inhibit HMGI activity *in vitro* by using transfected cells, classified in class 435, subclass 29.

3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05 (h)). In the instant case, the transgenic mice can be assay systems or models for HMGI lack of expression.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms. The method invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology. The protocols for making the mammal

and the protocols for administering antisense molecules are materially different and separate. In making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo. In the method of treating obesity, antisense molecules are administered to a developed mammal. Thus, the inventions are distinct and separate.

4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms. The method invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI. The protocols for making the mammal and the protocols for inhibiting the DNA binding activity of HMGI are materially different and separate. In making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo. In the method of treating obesity, a compound is administered to a developed mammal. Thus, the inventions are distinct and separate.

Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms. The method invention V is to a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein. The protocols for making the

mammal and the protocols for inhibiting the protein:protein interaction of HMGI protein are materially different and separate. In making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo. In the method of treating obesity, a compound is administered to a developed mammal. Thus, the inventions are distinct and separate.

Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms. The method invention VI is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols for making the mammal and the protocols for screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the inventions are distinct and separate.

Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the mammals of invention I can be used in assays to analyze the effect of HMGI absence on physiological mechanisms. The method invention VII is to a method of

screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols for making the mammal and the protocols for screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In making the mammal the HMGI gene is inactivated by introducing a disrupted HMGI gene to a fertilized embryo. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the inventions are distinct and separate.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene. The method of invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology. The protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and by inhibiting HMGI expression by antisense technology are materially different and separate. The protocol of invention II is breeding a developed mammal with an inactivated HMGI gene. In invention III, the protocol is administering antisense molecules to a developed mammal. Thus, the inventions are distinct and separate.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they

have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene. The method of invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI. The protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and by inhibiting the DNA binding activity of HMGI are materially different and separate. The protocol of invention II is breeding a developed mammal with an inactivated HMGI gene. In invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. Thus, the inventions are distinct and separate.

Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene. The method of invention V is to a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein. The protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and by inhibiting the protein:protein interaction of HMGI protein are materially different and separate. The protocol of invention II is breeding a developed mammal with an inactivated HMGI gene. In invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. Thus, the inventions are distinct and separate.

Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene. The method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. The protocol of invention II is breeding a developed mammal with an inactivated HMGI gene. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the inventions are distinct and separate.

Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). In the instant case the method of invention II is to a method of treating obesity by breeding a mammal with an inactivated HMGI gene. The method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by breeding a mammal with an inactivated HMGI gene and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially

different and separate. The protocol of invention II is breeding a developed mammal with an inactivated HMGI gene. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the inventions are distinct and separate.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology. The method of invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI. The protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and by inhibiting the DNA binding activity of HMGI are materially different and separate. In invention III, the protocol is administering antisense molecules to a developed mammal. In invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. The compound, reagents, dosages, composition of delivery, and route of delivery are different for each method. Thus, the inventions are distinct and separate.

Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01).

The method of invention III is to a method of treating obesity by inhibiting HMGI expression by antisense technology. The method of invention V is to a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein. The protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and by inhibiting the protein:protein interaction of HMGI protein are materially different and separate. In invention III, the protocol is administering antisense molecules to a developed mammal. In invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. The compound, reagents, dosages, composition of delivery, and route of delivery are different for each method. Thus, the inventions are distinct and separate.

Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention III is to a method of treating obesity *in vivo* by inhibiting HMGI expression by antisense technology. The method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In invention III, the protocol is administering antisense molecules to a developed mammal. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the

HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the inventions are distinct and separate.

Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention III is to a method of treating obesity *in vivo* by inhibiting HMGI expression by antisense technology. The method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by inhibiting HMGI expression by antisense technology and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In invention III, the protocol is administering antisense molecules to a developed mammal. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the inventions are distinct and separate.

Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention IV is to a method of treating obesity by inhibiting the DNA binding activity of HMGI. The method of invention V is to a method of treating obesity by inhibiting the

protein:protein interaction of HMGI protein. The protocols, reagents and techniques for a method of treating obesity by inhibiting the DNA binding activity of HMGI and by inhibiting the protein:protein interaction of HMGI protein are materially different and separate. In invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. In invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. The compound, reagents, dosages, composition of delivery, and route of delivery are different for each method. Thus, the inventions are distinct and separate.

Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention IV is to a method of treating obesity *in vivo* by inhibiting the DNA binding activity of HMGI. The method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by inhibiting the DNA binding activity of HMGI and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the inventions are distinct and separate.

Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention IV is to a method of treating obesity *in vivo* by inhibiting the DNA binding activity of HMGI. The method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by inhibiting the DNA binding activity of HMGI and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In invention IV, the protocol is administering a compound, for example, that inhibits the DNA binding activity of HMGI. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the inventions are distinct and separate.

Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention V is to a method of treating obesity *in vivo* by inhibiting the protein:protein interaction of HMGI protein. The method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by inhibiting the protein:protein interaction of HMGI

protein and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. Thus, the inventions are distinct and separate.

Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention V is to a method of treating obesity *in vivo* by inhibiting the protein:protein interaction of HMGI protein. The method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity *in vitro*. The protocols, reagents and techniques for a method of treating obesity by inhibiting the protein:protein interaction of HMGI protein and for a method of screening compounds' ability to inhibit HMGI activity *in vitro* are materially different and separate. In invention V, the protocol is administering a compound, for example, that inhibits the protein:protein interaction of HMGI protein. In the method of screening compounds' ability to inhibit HMGI activity *in vitro*, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. Thus, the inventions are distinct and separate.

Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (M.P.E.P. § 806.04, M.P.E.P. § 808.01). The method of invention VI is to a method of screening compounds' ability to inhibit HMGI activity *in vitro* using a solid support. The method of invention VII is to a method of screening compounds' ability to inhibit HMGI activity *in vitro* using a transfected cell. The protocols, reagents and techniques for a method of screening compounds' ability to inhibit HMGI activity *in vitro* using a solid support and using a transfected cell are materially different and separate. In invention VI, the protocol is: HMGI protein is immobilized on a solid surface, a compound is added, and binding affinity is measured. In invention VII, the HMGI gene and a reporter gene are transfected into a cell, a compound is added, and levels of expression of HMGI are measured using the reporter gene product. The apparatus, reagents, techniques, equipment and protocols are different for each method. Thus, the inventions are distinct and separate.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for Groups I-VII are not required each other, restriction for examination purposes as indicated is proper.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. A telephone call was made to Richard R. Muccino on July 16, 1998 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson whose telephone number is (703) 305-0120.

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

MCW

July 21, 1998